SECTION 5: 510(k) SUMMARY

MAY - 2 2008

AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

Applicant: ConvaTec
A Division of E. R. Squibb & Sons, LLC
200 Headquarters Park Drive
Skillman, New Jersey 08558

Contact: Marilyn Konicky
Associate Director, US and International Regulatory Affairs
908-904-2541
fax: 908-904-2235
email: marilyn.konicky@bms.com

Device: AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Substantially Equivalent Device: AQUACEL® Hydrofiber® Wound Dressing
K943258, K982116, K063271

AQUACEL®Ag Hydrofiber® (Silver Impregnated Antimicrobial Dressing) is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose and 1.2% ionic silver which allows for a maximum of 12mg of silver for a 4 inch x 4 inch dressing. The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.

AQUACEL® Ag dressing is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions and lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, AQUACEL® Ag dressing may be used for more serious wounds such as diabetic foot and leg ulcers, pressure ulcers (partial and full-thickness), surgical wounds or traumatic wounds left to

heal by secondary intent, and partial thickness burns (second degree), wounds that are prone to bleeding, oncology wounds and management of painful wounds.

AQUACEL® Ag Hydrofiber® Dressing is indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that, as a protocol of care, may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria provided by AQUACEL® Ag Dressings support the body's healing process and help reduce the risk of wound infection.

A majority of postoperative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of non-adherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

A careful and thorough review of the literature suggests that Hydrofiber® dressings have been used safely and effectively in clinical trials for the management of surgical incisions healing with primary intent. The capacity to absorb, conform and the relative ease of removal are important attributes of AQUACEL® Ag, which probably play an important role in healing by primary intent for surgical wounds. Hydrofiber® dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintain a moist environment for wound healing. All the studies which have been reviewed suggest that, compared to standard dressings, using a Hydrofiber® dressing (AQUACEL®) leads to significantly less dressing changes.

In addition, reduction in blister formation, hematoma and edema and decreased pain were observed in some of the studies. It is important to note that a majority of the clinical trials were randomized controlled trials. More importantly, there were no undue safety concerns which were observed in the trials. Although the studies were predominantly in orthopedic surgery, utilization of Hydrofiber® dressings (AQUACEL®) in vascular surgery also has been discussed.

Based on the evidence provided, we propose that Hydrofiber® based products (AQUACEL® dressings and AQUACEL® Ag dressings) can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent. A brief summary of some of the clinical information follows:

AQUACEL® hydrofiber dressing has been shown to be safe and effective as a primary dressing on surgical incisions which heal by primary intent. The studies consisted of randomized, controlled, clinical trials in hip, knee and arthroplasty surgeries comparing the use of AQUACEL® / Tegaderm™ to control treatment. AQUACEL® /Tegaderm™

was used as a primary dressing in hip and knee surgeries compared to control in 183 patients (85 patients were randomized to AQUACEL® / Tegaderm™ and 98 patients to control) and the results demonstrated that AQUACEL® / Tegaderm™ was 5.8 times more likely to result in a wound with no complications than control* (95% CI 2.8-12.5; $p<0.00001$). Dressing pain score was statistically lower for patients on AQUACEL® / Tegaderm™ dressing compared to control[1] ($p<0.001$). AQUACEL® was compared to control treatment when used as a primary dressing for orthopedic wounds left to heal by primary intention following lower limb arthroplasty. This study evaluated the number of dressing changes post surgery in 61 patients (30 patients were allocated to the AQUACEL® hydrofiber dressing group and 31 patients to the control group). Dressing changes were required in (43%) patients in the AQUACEL® hydrofiber dressing group compared to (77%) patients in the control group ($p=0.001$)[2]. In addition, the use of AQUACEL® hydrofiber as a primary dressing was compared to conventional dressings in a randomized clinical trial in 100 hip replacement patients (50 patients were randomized to AQUACEL® hydrofiber dressing and 50 patients were randomized to control). In this study, dressing changes were fewer with the use of AQUACEL® hydrofiber dressing potentially limiting mechanical irritation and damage to the wound[3]. In conclusion, the studies demonstrate that AQUACEL® hydrofiber dressing is safe and effective as a primary dressing on surgical incisions which heal by primary intent. For more details regarding the studies, please see the following references:

References

1. Ravenscroft MJ, Harker J, Buch KA. A Prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: AQUACEL® and Tegaderm™ versus Cutiplast*. *Ann R Coll Surg Engl* 2006; 88: 18-22
2. Abuzakuk T, Coward P, Sheneva Y, Kumar S, Skinner JA. The management of wounds following primary lower limb arthroplasty: a prospective randomized study comparing hydrofiber® and central pad dressing. *Int Wound J* 2006; 3; 133-137
3. Harle S, Korhonen A, Jyrki A et al. A randomized clinical trial of two different wound dressing materials for hip replacement patients. *Journal of Orthopedic Nursing (2005)* 9, 205-210

Additional clinical information can be found in Section 20: Performance Testing-Clinical.

*Cutiplast is a trademark of Smith & Nephew
Tegaderm™ is a trademark of 3M Company
AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing are registered trademarks of E.R. Squibb & Sons, L.L.C.

SECTION 5: 510(k) SUMMARY

AQUACEL® Hydrofiber® Wound Dressing

Applicant: ConvaTec
A Division of E. R. Squibb & Sons, LLC
200 Headquarters Park Drive
Skillman, New Jersey 08558

Contact: Marilyn Konicky
Associate Director, US and International Regulatory Affairs
908-904-2541
fax: 908-904-2235
email: marilyn.konicky@bms.com

Device: AQUACEL® Hydrofiber® Wound Dressing

Classification Name: Dressing, Wound, Hydrophilic

Device Class: Class I

Product Code: NAC

Substantially Equivalent Device: AQUACEL® Hydrofiber® Wound Dressing
K943258, K982116, K063271

AQUACEL®Hydrofiber® Wound Dressings are soft, sterile, non-woven pad or ribbon dressings composed of hydrocolloid fibers (sodium carboxymethylcellulose). These conformable and highly absorbent dressings absorb wound fluids and create a soft gel which maintains a moist environment which supports the body's healing process.

AQUACEL® dressing is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions, lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, AQUACEL® dressing may be used for more serious wounds such as leg ulcers, pressure ulcers (Stages II-IV), diabetic ulcers, surgical wounds, donor sites, second degree burns, wounds that are prone to bleeding and the management of painful wounds.

The Hydrofiber® technology in AQUACEL® dressings aids in removing necrotic material from the wound without damaging newly formed tissue. AQUACEL® dressings are currently indicated for the management of post-operative surgical wounds and surgical or traumatic wounds that have been left to heal by secondary intention.

A majority of post-operative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of non-adherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

A careful and thorough review of the literature suggests that Hydrofiber® dressings have been used safely and effectively in clinical trials for the management of surgical incisions healing with primary intent. The capacity to absorb, conform and the relative ease of removal are important attributes of AQUACEL® which probably play an important role in healing by primary intent for surgical wounds. Hydrofiber® dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintains a moist environment for wound healing. All the studies which have been reviewed suggest that, compared to standard dressings, using AQUACEL® leads to significantly less dressing changes.

In addition, reduction in blister formation, hematoma and edema and decreased pain were observed in some of the studies. It is important to note that a majority of the clinical trials were randomized controlled trials. More importantly, there were no undue safety concerns which were observed in the trials. Although the studies were predominantly in orthopedic surgery, utilization of AQUACEL® dressings in vascular surgery also has been discussed.

Based on the evidence provided, we propose that Hydrofiber® based products can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent. A brief summary of some of the clinical information follows:

AQUACEL® hydrofiber dressing has been shown to be safe and effective as a primary dressing on surgical incisions which heal by primary intent. The studies consisted of randomized, controlled, clinical trials in hip, knee and arthroplasty surgeries comparing the use of AQUACEL® / Tegaderm™ to control treatment. AQUACEL® /Tegaderm™ was used as a primary dressing in hip and knee surgeries compared to control in 183 patients (85 patients were randomized to AQUACEL® / Tegaderm™ and 98 patients to control) and the results demonstrated that AQUACEL® / Tegaderm™ was 5.8 times more likely to result in a wound with no complications than control* (95% CI 2.8-12.5; $p<0.00001$). Dressing pain score was statistically lower for patients on AQUACEL® / Tegaderm™ dressing compared to control[1] ($p<0.001$). AQUACEL® was compared to control treatment when used as a primary dressing for orthopedic wounds left to heal by primary intention following lower limb arthroplasty. This study evaluated the number of dressing changes post surgery in 61 patients (30 patients were allocated to the AQUACEL® hydrofiber dressing group and 31 patients to the control group). Dressing

changes were required in (43%) patients in the AQUACEL® hydrofiber dressing group compared to (77%) patients in the control group (p=0.001)[2]. In addition, the use of AQUACEL® hydrofiber as a primary dressing was compared to conventional dressings in a randomized clinical trial in 100 hip replacement patients (50 patients were randomized to AQUACEL® hydrofiber dressing and 50 patients were randomized to control). In this study, dressing changes were fewer with the use of AQUACEL® hydrofiber dressing potentially limiting mechanical irritation and damage to the wound[3]. In conclusion, the studies demonstrate that AQUACEL® hydrofiber dressing is safe and effective as a primary dressing on surgical incisions which heal by primary intent. For more details regarding the studies, please see the following references.

References

1. Ravenscroft MJ, Harker J, Buch KA. A Prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: AQUACEL® and Tegaderm™ versus Cutiplast*. *Ann R Coll Surg Engl* 2006; 88: 18-22
2. Abuzakuk T, Coward P, Sheneva Y, Kumar S, Skinner JA. The management of wounds following primary lower limb arthroplasty: a prospective randomized study comparing hydrofiber® and central pad dressing. *Int Wound J* 2006; 3; 133-137
3. Harle S, Korhonen A, Jyrki A et al. A randomized clinical trial of two different wound dressing materials for hip replacement patients. *Journal of Orthopedic Nursing (2005)* 9, 205-210

Additional clinical information can be found in Section 20: Performance Testing-Clinical.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Convatec, Division of ER
Squibb & Sons, LLC
% Ms. Marilyn Konicky
Associate Director
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K080383
Trade/Device Name: AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing
AQUACEL® Hydrofiber® Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO, NAC
Dated: February 8, 2008
Received: February 12, 2008

Dear Ms. Konicky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT, CONTINUED

510(K) Number (if known): K080383

Device names: AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

For Over-the-Counter Use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL® Ag Hydrofiber Dressing may be used for the management of:

- Wounds as an effective barrier to bacterial penetration **of the dressing as this may** help reduce infection
- Partial thickness (second degree) burns
- Diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness)
- Surgical wounds left to heal by secondary intention **such as dehisced surgical incisions**[1]
- **Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- Traumatic wounds
- Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided **and donor sites**[1]
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- **Infected Wounds**[1]

[1]Clarified / New Indication, not previously included in this format under K013814 or K063271

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-the-Counter Use** ____X____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080383

SECTION 4: INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K080383

Device name: AQUACEL® Hydrofiber® Wound Dressing

For Over-the-Counter Use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL® Hydrofiber® Wound Dressing may be used for the management of:

- Leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- Surgical wounds (post-operative, donor sites, dermatological)
- Partial thickness (second degree) burns
- Traumatic or surgical wounds left to heal by secondary intention **such as dehisced surgical incisions**[1]
- **Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]
- Local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites
- Management of painful wounds

[1] **Clarified / New Indication, not previously included in the format under K943258, K982116, or K063271**
[2] **Indication re-positioned within Indications for Use statement**

Prescription Use ___X___ **AND/OR** (Part 21 CFR 801 Subpart D)

Over-the-Counter Use ___X___ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080383